

Interview Summary	Application No.	Applicant(s)	
	09/710,239	CHANG ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

All participants (applicant, applicant's representative, PTO personnel):

- (1) Chih-Min Kam. (3) Jim Nesbitt.
 (2) Leanne Price. (4) Jon Weber.

Date of Interview: 07 December 2004.

Type: a) ☐ Telephonic b) ☐ Video Conference
 c) ☒ Personal [copy given to: 1) ☐ applicant 2) ☒ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☐ No.
 If Yes, brief description: _____.

Claim(s) discussed: 4, 12, 89 and 98.

Identification of prior art discussed: _____.


Agreement with respect to the claims f) ☐ was reached. g) ☒ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Discussing the rejection under 35 U.S.C. 102(e) and 112, second paragraph; applicants will remove the term "homogeneous" and amend the claims with the limitations having more clearly definition in the amendment.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.


 Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

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12/7/04 10:00 AM

COVER SHEET

The attached transmission contains information of a confidential and proprietary nature subject to attorney-client privilege and is intended only for review by the addressee named below.

Date: 3 December 2004

To: Examiner Kam
Group 1653
Fax No. 571-273-0948

Jim Neabitt

From: Leanne C. Price

No. of pages, including cover sheet: 7

As discussed, an informal list of pending claims and proposed amendments for you to consider prior to our meeting next Tuesday, December 7th, at 10 am.

Please call Carolyn Caires at 650-866-7323 if there are any problems with transmission of this document.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Chang et al.	Assignee:	FibroGen, Inc.
Title:	RECOMBINANT GELATINS		
Serial No.:	09/710,239	Filing Date:	10 November 2000
Examiner:	C. Kam	Group Art Unit:	1653

INFORMAL COMMUNICATION

Dear Examiner Kam:

Thank you for your courtesies in our phone conversations of 24 November and 1 December 2004. As discussed, here is an informal listing of the pending claims, including suggested amendments. We look forward to discussing the case with you further this coming Tuesday, December 7.

As a reminder, claims 2-6, 8, 12, 21, 30, 43-45, 47, 48, 50, 54-57, 59, 61, 62, 64-68, 70-73, 75-83, 89, 90, 92-94, and 98 are pending, and we propose to add new claim 99. Claims 5, 6, 30, 43-45, 47, 48, 50, 54-57, 59, 62, 64-68, 70-73, 76-83, 92-94 are allowable. Claims 2, 3, 8, 12, 21, 61, 75, and 98 were provisionally rejected in the previous Office Action, and we have accordingly filed a terminal disclaimer to appropriately address this issue. Claims 3, 89, and 98 were rejected under 35 U.S.C. 112, 2nd paragraph; the rejected language does not appear in these claims as we propose below to amend them. Claims 4, 12, and 90 were rejected under 35 U.S.C. 102(e), and we look forward to presenting to you arguments that clearly distinguish the claimed subject matter from the disclosure of that reference.

IN THE CLAIMS

The suggested amendments to the claims are indicated below.

3. A recombinant human gelatin having a molecular weight range selected from the group consisting of about 0 1 to 50 kDa, about 50 to 100 kDa, about 100 to 150 kDa, about 150 to 200 kDa, about 200 to 250 kDa, about 250 to 300 kDa, and about 300 to 350 kDa.
4. ~~A~~ An isolated recombinant gelatin having a molecular weight greater than 300 kDa.

Docket No. FP0400 US

12. ~~A composition comprising a recombinant gelatin, wherein the recombinant gelatin comprises~~ comprising homogeneous recombinant gelatin polypeptides.
89. A composition comprising a recombinant human gelatin, wherein the recombinant human gelatin is produced directly from ~~an altered collagen construct~~ expression of a polynucleotide sequence that encodes at least one collagenous domain and that does not encode naturally occurring collagen.
98. A pharmaceutical composition comprising a recombinant human gelatin, wherein the recombinant human gelatin is produced directly from ~~an altered collagen construct~~ expression of a polynucleotide sequence that encodes at least one collagenous domain and that does not encode naturally occurring collagen.

We propose adding the following new claim, which contains no added subject matter.

99. A recombinant gelatin comprising recombinant gelatin polypeptides having a uniform molecular weight.

The polynucleotide sequence of amended claims 89 and 98 finds support throughout the specification, for example, at least at page 12, lines 7-9; page 13, lines 14-15; and page 23, lines 20-23 of the specification as filed. The amendments to claims 3, 4, and 12 are made to clarify the claimed invention. Support for the recombinant gelatin of new claim 99 is found throughout the specification at, e.g., page 30, lines 38-39; page 31, line 27; etc.

For your convenience, we have attached as an appendix a list of the pending claims complete with the amendments suggested above. Please do not hesitate to call me directly at 650-866-7254 with any questions or comments.

Kind regards,

Date:

3 December 04

By:



Leanne C. Price
Reg. No. 42,090

APPENDIX

2. A recombinant human gelatin having a molecular weight selected from the group consisting of about 1 kDa, about 5 kDa, about 8 kDa, about 9 kDa, about 10 kDa, about 14 kDa, about 16 kDa, about 18 kDa, about 20 kDa, about 22 kDa, about 23 kDa, about 29 kDa, about 33 kDa, about 36 kDa, about 41 kDa, about 44 kDa, about 50 kDa, and about 65 kDa.
3. A recombinant human gelatin having a molecular weight range selected from the group consisting of about 1 to 50 kDa, about 50 to 100 kDa, about 100 to 150 kDa, about 150 to 200 kDa, about 200 to 250 kDa, about 250 to 300 kDa, and about 300 to 350 kDa.
4. An isolated recombinant gelatin having a molecular weight greater than 300 kDa.
5. A recombinant human gelatin having a Bloom strength selected from the group consisting of 50, 100, 150, 200, 250, and 300.
6. A recombinant human gelatin having a Bloom strength of between 0 and 100.
8. A composition comprising a recombinant gelatin, wherein the recombinant gelatin has a percentage hydroxylation selected from the group consisting of greater than 0% to 20%, 20 to 80%, and 80 to 100%.
12. A recombinant gelatin comprising homogeneous recombinant gelatin polypeptides.
21. A recombinant gelatin comprising the amino acid sequence of SEQ ID NO:18.
30. A recombinant gelatin comprising the amino acid sequence of SEQ ID NO:29.
43. An encapsulant comprising a recombinant human gelatin.
44. A stabilizing agent comprising a recombinant human gelatin.

45. A film-forming agent comprising a recombinant human gelatin.
47. An emulsifier comprising a recombinant human gelatin.
48. A thickening agent comprising a recombinant human gelatin.
50. A colloidal agent comprising a recombinant human gelatin.
54. A hard gel capsule comprising a recombinant human gelatin.
55. A soft gel capsule comprising a recombinant human gelatin.
56. A plasma expander comprising a recombinant human gelatin.
57. A colloidal volume replacement material comprising a recombinant human gelatin.
59. A medical sponge comprising a recombinant human gelatin.
61. A pharmaceutical stabilizer comprising a recombinant human gelatin.
62. A microcarrier comprising a recombinant human gelatin.
64. An edible composition comprising a recombinant human gelatin.
65. A protein supplement comprising a recombinant human gelatin.
66. A fat substitute comprising a recombinant human gelatin.
67. A nutritional supplement comprising a recombinant human gelatin.
68. An edible coating comprising a recombinant human gelatin.
70. A photographic composition comprising a recombinant human gelatin.

71. A cosmetic composition comprising a recombinant human gelatin.
72. An industrial composition comprising a recombinant human gelatin.
73. A cell culture composition comprising a recombinant human gelatin.
75. The pharmaceutical stabilizer of claim 61, wherein the pharmaceutical stabilizer is a vaccine stabilizer.
76. A recombinant human gelatin having a molecular weight range selected from the group consisting of about 10 to 30 kDa, about 30 to 50 kDa, and about 50 to 70 kDa.
77. A recombinant human gelatin having a molecular weight range selected from the group consisting of about 10 to 70 kDa, about 150 to 250 kDa, and about 250 to 350 kDa.
78. A composition comprising a recombinant gelatin, wherein the recombinant gelatin has a percentage hydroxylation selected from the group consisting of 20 to 40%, 40 to 60%, and 60 to 80%.
79. A composition comprising a recombinant gelatin, wherein the recombinant gelatin has a percentage hydroxylation selected from the group consisting of 20 to 30%, 30 to 40%, and 40 to 80%.
80. A composition comprising a recombinant gelatin, wherein the recombinant gelatin has a percentage hydroxylation of 30 to 80%.
81. A composition comprising a recombinant gelatin, wherein the recombinant gelatin has a percentage hydroxylation of 20 to 60%.
82. A composition comprising a recombinant gelatin, wherein the recombinant gelatin has a percentage hydroxylation of 30 to 60%.
83. A composition comprising a recombinant gelatin, wherein the recombinant gelatin has a percentage hydroxylation selected from the group consisting of greater than 0% to 20%,

20 to 80%, and 80 to 100%, and further wherein the hydroxylation is proline hydroxylation.

89. A composition comprising a recombinant human gelatin, wherein the recombinant human gelatin is produced directly from expression of a polynucleotide sequence that encodes at least one collagenous domain and that does not encode naturally occurring collagen.
90. A pharmaceutical composition comprising a recombinant gelatin, wherein the recombinant gelatin comprises homogeneous recombinant gelatin polypeptides.
92. A pharmaceutical composition comprising a recombinant human gelatin, wherein the recombinant human gelatin is non-hydroxylated.
93. A pharmaceutical composition comprising a recombinant gelatin, wherein the recombinant gelatin has a percentage hydroxylation selected from the group consisting of greater than 0 to 20%, 20 to 80%, and 80 to 100%.
94. The pharmaceutical composition of claim 93, wherein the hydroxylation is proline hydroxylation.
98. A pharmaceutical composition comprising a recombinant human gelatin, wherein the recombinant human gelatin is produced directly from expression of a polynucleotide sequence that encodes at least one collagenous domain and that does not encode naturally occurring collagen.
99. A recombinant gelatin comprising recombinant gelatin polypeptides having a uniform molecular weight.